

## **REMARKS**

Claim 15 has been amended. Upon entry of this amendment, claims 15-30 will remain pending in the present application.

### **I. Claim Amendments**

Claim 15 has been amended to introduce two clarifications to the claim language. First, the language “are adapted to” has been deleted to make it clear that the distal ends of the arms support at least a portion of said hollow structures and hold the joining elements while positioning at least one hollow structure relative to the joining elements for making an anastomosis between the hollow structures. Second, the phrase “and said positioning of said hollow structures is accomplished” has been added to clarify that positioning of the hollow structures is accomplished by moving the arms from the first position to the second position.

### **II. The Rejection Under 35 U.S.C. 102(e)**

Claims 15-30 have been rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent no. 5,720,755 (Dakov). This rejection, at least insofar as it applies to claims 15-30, as amended, is traversed and reconsideration is requested for the reasons which follow.

The applicator of the present claims 15-30 is adapted for anastomosis via two distinct actions which are carried out sequentially:

1. Tissue presentation which is done by expansion of the applicator and movement of the arms from a first position to a second position, and
2. Tissue bonding which is done by permanently deforming the joining elements.

This two-step sequence has proven, in practice, to be extremely important since proper tissue presentation by device and arm expansion, to position the vessel walls around the applicator, positions the vessel walls for deployment of the staples to make the connection. This method minimizes errors in tissue capture by the staples (e.g. missing a part of the vessel wall – See page 13, lines 25-28 of the specification) thereby greatly enhancing the reliability of the anastomosis.

The arms of the device of figures 12A-12F of Dakov do not position the tissue of the vessel around the applicator or relative to the joining elements by movement of the arms from the first position to the second position before penetrating the tissue with the staples. First, the arms of the Dakov device do not contact the hollow tissue structure at all, which instead is positioned on the outside of static tube

204. In addition, the staples 206 of Dakov are moved outwardly to penetrate the tissue by the expansion of arms 214b. See e.g. col. 12, lines 21-30 of Dakov. Therefore, the hollow tissue structure is already positioned for stapling prior to expansion of the arms of the device of Dakov since stapling, not positioning, occurs during expansion of the arms of the device. Dakov cannot first position the tissue around the static tube 204 of the applicator by expansion of the arms since the movable arms of the device of figures 12C-12F of Dakov are surrounded by the static tube 204, preventing the arms from carrying out such a function.

Claim 15, as amended, distinguishes over the device of figures 12A-12E of Dakov since claim 15 requires that the distal ends of the arms support at least a portion of the hollow structures and hold the joining elements while positioning at least one said hollow structure relative to the joining elements for making an anastomosis between the hollow structures. Claim 15 also requires that the positioning of the hollow structures is accomplished by moving the arms from the first position to the second position.

The device of Dakov does not position at least one hollow structure relative to said joining elements by movement of the arms from the first position to the second position since the arms of Dakov are incapable of carrying out this function due to the presence of static tube 204 surrounding the device. Rather, the hollow tissue structures are already positioned around static tube 204 of Dakov prior to expansion of the arms since expansion of the arms of Dakov accomplishes stapling of the hollow tissue structures and not positioning.

The Examiner takes the position that,

“The arms [of Dakov] are adapted to hold and position said joining elements for making an anastomosis between the hollow structures. See figures 12C, 12E-F. The arms are capable of support [sic] a portion of the hollow structure. Since ref. 212 are openings allowing access to the interior of the detainer, the hollow structure could be pulled in through the opening and be supported by the arms. The arms also have open spaces that the tissue could be wrapped around.” See page 3 of the Final Rejection.

Claim 15 has been amended to delete the phrase, “are adapted to” such that claim 15 now requires that the arms support and position a hollow structure relative to the joining elements by movement of the arms from the first to the second position. This feature is nowhere disclosed in Dakov.

In addition, the Examiner’s position that the hollow structure could be pulled in through the openings 212 and wrapped around the arms of the device of Figures 12C-12F of Dakov is pure speculation and is nowhere supported by the disclosure of Dakov. The skilled person would have no

reason to pull the hollow tissue structure through the openings 212 of Dakov nor any reason to wrap the hollow tissue structure around the arms of the device of Dakov since Dakov the hollow tissue structures are already correctly positioned for joining by the device of Dakov by locating the hollow tissue structures on the outside of static tube 204. Thus, there is absolutely no need to carry out the further steps of pulling the hollow tissue structures into openings 212 or wrapping the hollow tissue structures around the arms of the Dakov device.

Also, it does not appear to be possible to pull the hollow tissue structure through the openings 212 of Dakov and wrap the hollow tissue structure around the arms of Dakov since there does not appear to be a way to reach out from within openings 212 in order to pull the hollow tissue structure into the openings 212. Even if this were possible, it is extremely likely that the hollow tissue structure would be damaged by, for example, tearing, since openings 212 are spaced apart from one another. Pulling a single hollow tissue structure through multiple openings 212 would require significant deformation of the hollow tissue structure which would likely cause damage.

The Examiner also takes the position that if the hollow tissue structures were pulled through the openings 212 of Dakov and wrapped around the arms, the joining elements would still be capable of piercing the tissue and forming an anastomosis between the hollow structures. However, the Examiner has not explained where the first and second hollow structures are positioned to accomplish the joining using this method. In addition, the Examiner has not explained how it would be possible to extract the joined hollow structures from the arms and openings 212 of Dakov once they have been joined in this manner. This would appear to be impossible since the joining would not allow the portion of the tissue wrapped around the arms to be unwrapped for removal from the openings 212 of Dakov.

Finally, even if the Examiner's speculative methodology were carried out, it still does not meet the limitations of the present claims because the movement of the arms of Dakov would still not position the hollow tissue structure for joining. Rather, in Dakov, joining occurs at the location of the openings 212. Thus, the portion of the hollow tissue structure that is joined would already have been located at the openings 212 prior to movement of the arms of the device of Dakov and thus would not have been positioned by the arms, as presently claimed. In fact, this portion of the hollow tissue structure would not contact the arms of the device of Dakov at all. Rather, expansion of the arms would only cause contact of the staples with the hollow tissue structure at this location. Thus, positioning of the hollow structures for joining would not be accomplished by the arms, as presently claimed in claim

15, but instead by pulling the hollow tissue structures through openings 212 of Dakov. Therefore, the present claims would not be met by the Examiner's speculative interpretation of Dakov.

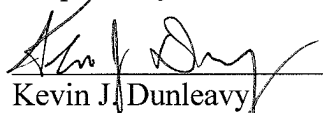
Accordingly, for at least this reason, claim 15 is considered to be novel over Dakov. Claims 16-30 all depend from claim 15 and thus are considered to be novel over Dakov for at least the same reason as claim 15, as amended. Favorable consideration and withdrawal of the novelty objection over Dakov is requested.

In addition, claims 15-30 are considered to be unobvious over Dakov since a skilled person would have no reason to remove static tube 204 from the device of figures 12A-12F of Dakov, as would be required to meet the limitations of the present claims, as discussed above. One reason for this is that static tube 204 includes predefined passages for guiding the movement of arms 214 and staples 206 in the device of Dakov and thus without such predefined passages in the static tube 204, the device of Dakov would not function.

Also, the device of figures 12A-12F of Dakov is not suitable for a two-step anastomosis, as is the presently claimed applicator. More particularly, the device of Dakov, due to its design, must penetrate the vessel wall with the staples while expanding the arms since expansion of the arms is the mechanism which causes the staples to penetrate the tissue. In the present device, the staples do not have to penetrate the tissue as a result of the expansion of the arms, but rather can be made to penetrate the tissue as a result of a separate step, namely, movement of the detainer. This allows a two-step process of first positioning the tissue and second penetrating the tissue with staples, in order to provide a more reliable connection due to less staples missing the vessel walls.

Favorable consideration and issuance of a Notice of Allowance is requested.

Respectfully submitted,

  
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